

# House Committee on Oversight and Reform Hearing on Drug Pricing Novartis Written Statement – Tom Kendris

## Statement by Thomas N. Kendris U.S. Country President for Novartis Before the U.S. House of Representatives Committee on Oversight and Reform October 1, 2020

Chairwoman Maloney, Ranking Member Comer, and Members of the Committee, thank you for the opportunity to submit this testimony.

My name is Tom Kendris and I am the U.S. Country President for Novartis.

In 1995, I joined Ciba-Geigy, a predecessor company of Novartis, and in my 25 years at the company I have served in a number of legal and management positions. In my current role as U.S. Country President, I have oversight across all Novartis U.S. group companies, including our Innovative Medicines division in East Hanover, New Jersey, Sandoz, our generics business in Princeton, New Jersey, and the Novartis Institutes for Biomedical Research in Cambridge, Massachusetts.

Prior to joining Novartis, I was an attorney in private practice as well as an Assistant District Attorney for nine years with the New York County District Attorney's Office, under Manhattan District Attorney Robert M. Morgenthau.

Novartis is a global developer and manufacturer of pharmaceutical products. We use innovative science and digital technologies to develop transformative medicines that improve and extend people's lives. We also produce generic drugs and biosimilars through our Sandoz division, the third-largest generics company in the U.S.

Our medicines reach close to 800 million people every year, treating diseases including cancer, heart disease, autoimmune diseases, respiratory illnesses, neurological conditions, and several rare diseases.

In the U.S., we employ approximately 15,000 associates, including scientists, physicians, and business professionals, and we support more than 100,000 additional jobs at small, medium, and large U.S. businesses. In the U.S., we operate in all 50 states, the District of Columbia, and Puerto Rico, with five headquarter campuses, six research facilities, including our global R&D headquarters, and eight operational sites.

### 1. Delivering Transformative Innovation

#### A. *The Novartis Commitment*

We devote an enormous amount of resources to researching and developing innovative medicines. For more than ten years, we have been among the world's top 20 spenders in R&D across all industries. Novartis invests more than 18% of its global revenue in R&D. In 2019, we invested \$9.4 billion, \$3.9 billion of which was specifically invested in the U.S. We employ more than 23,000 scientists, physicians, and business professionals in R&D worldwide, including

5,000 employees here in the U.S., of which 2,200 work out of the Novartis Institutes for Biomedical Research in Cambridge, Massachusetts.

This sustained commitment to R&D has yielded life transforming results. Our pipeline, with more than 200 projects in clinical development and more than 500 clinical trials in progress, is consistently rated as one of the most respected in the industry. Over the past five years, Novartis has received 18 breakthrough therapy designations from the FDA for medications that treat conditions including sickle cell disease, lung cancer, and breast cancer. The FDA's designation of a therapy as a "breakthrough" reflects the agency's determination that the medicine is intended to treat a serious condition and that the medicine may provide substantial improvement over currently available therapies.

Novartis also is consistently recognized for its commitment to innovation. Novartis was recently named to the Boston Consulting Group's list of the Top 50 Most Innovative Companies and ranked third on IdeaPharma's Pharmaceutical Innovation Index. In 2018, Novartis was ranked as the most innovative biotech company and the 21<sup>st</sup> most innovative company overall by Fast Company.

Today, our scientists are pioneers on the cell and gene therapy frontier, working at the edge of possibility with emerging tools to bring entirely new types of treatments to patients with devastating diseases, including genetic disorders and deadly cancers.

In cell therapies, we developed the first CAR-T therapy to treat a rare form of pediatric and young adult leukemia. This therapy reprograms a person's own immune cells to fight their cancer and can bring a patient from the brink of death to remission. The first patient ever to receive this therapy has been cancer free for eight years and is going to high school and living a normal life. Getting to know this young patient and her family is one of the great privileges of my career.

We have also developed a gene therapy to treat spinal muscular atrophy, a rare, genetic neuromuscular disease that primarily affects babies. The treatment is one of the first gene therapies to be approved in the U.S. After only a one time intravenous injection, babies who would have otherwise died by the age of two or three are going to kindergarten and growing up like any other kids.

Beyond rare diseases and cancers, we are reimagining how innovative medicines might improve public health broadly, particularly in sickle cell, malaria, and cardiovascular disease.

And our leadership in novel technologies extends to other areas as well. For example, our researchers are developing radioligand therapies that deliver radiation to cancer cells in targeted and precise ways.

Other significant investments include an experimental immunomodulatory therapy with the potential to make kidney and liver transplants more durable, and a novel molecule designed to alter messenger RNA, which has the potential to be the first medicine approved to treat patients with elevated levels of lipoprotein(a) and established cardiovascular disease.

The extraordinary R&D work our associates are doing today builds on almost a century of sustained innovation in many therapeutic areas, including oncology, organ transplantation, cardiology, multiple sclerosis, and respiratory.

## *B. Gleevec*

Our long history of innovative and life-changing medical breakthroughs includes the drug we were invited here to discuss today – Gleevec, which was first approved in 2001.

We are extremely proud to have discovered, developed, and brought to market Gleevec (imatinib mesylate) – a life-changing, scientific breakthrough that transformed chronic myeloid leukemia (“CML”) from a fatal condition into a manageable disease. Before Gleevec, the five-year survival rate for someone with CML was only 30 percent. With the introduction of Gleevec in 2001, the annual death rate of CML patients was reduced by 74 percent in the first five years following launch. Today, in large part because of Gleevec, the vast majority of CML patients have a normal lifespan.

Gleevec was the first of many new therapies developed through an advanced understanding of the molecular biology of cancer. It was also the world’s first targeted cancer therapy and revolutionized the field of cancer medicine. The remarkable story of Gleevec began with the discovery of the Philadelphia chromosome, the first consistent genetic abnormality ever recognized in cancer. CML occurs because of that genetic malfunction. Put simply, two genes, which normally produce two separate proteins, become fused together. They produce a single faulty protein, Bcr-Abl, which triggers the body to produce too many white blood cells. Gleevec was designed to bind to and stop this deadly protein.

For over a decade, Novartis committed extensive resources to discover, develop, and obtain FDA approval for Gleevec. In the early 1990s, after years of intensive efforts, researchers at Novartis (then Ciba-Geigy) identified several Bcr-Abl inhibitors. Many years of additional research and investment ultimately led to the discovery of the new compound that would eventually become Gleevec. When the efficacy of Gleevec in treating CML patients became evident, we made every effort to get Gleevec to patients who desperately needed it.

Since the drug’s initial approval in 2001 for the treatment of late-stage CML, we developed Gleevec for six additional uses in rare cancers, including gastrointestinal stromal tumors (GIST). Our studies showed the longest survival ever observed in certain patients with this deadly disease and provided patients with an adjuvant treatment option to reduce their risk of recurrence following surgery.

Placing patients at the heart of what we do, our extensive additional investments resulted in the expansion of the initial indications to earlier stages of CML and GIST, as well as the following rare cancers for which Gleevec obtained orphan drug status:

- PH+ Acute lymphoblastic leukemia;
- Myelodysplastic syndrome (MDS)/Myeloproliferative disorder (“MDS”);
- Aggressive systemic mastocytosis (“ASM”);
- Hypereosinophilic syndrome (“HES”); and
- Metastatic dermatofibrosarcoma protuberans (“DFSP”).

In 2016, Novartis was awarded the Prix Galien Foundation “Discovery of the Decade” Award for Best Pharmaceutical Product for Gleevec. Considered “the pharmaceutical industry’s Nobel Prize,” the Prix Galien rewards excellence in scientific innovation that improves the state of human health.

Given its life-changing attributes, we have committed to making Gleevec accessible to patients who need it. Prior to the introduction of generic alternatives in 2016, the majority of patients in the U.S. paid less than \$100 out of pocket per month for Gleevec, and that remains the case today. There has been no price increase on Gleevec in over five years, and today 40% of the drug is produced for donation purposes.

## 2. Our Approach to Pricing and Access

### A. Shaping a More Sustainable U.S. Healthcare System

While we are focused on tackling some of the most intractable medical problems through the development of transformative medicines, Novartis' leadership also recognizes that these innovations are immaterial if patients cannot afford them or otherwise access them.

In the U.S., issues of price and access present systemic challenges that must be addressed by industry and policy makers, and we are committed to being a part of the solution. For 2020, we expect the average net price of our medicines to decrease by 2.5% across our product portfolio, and from 2016-2019 the net price decreases of our products in the U.S. ranged from 2% to 2.6%. For comparison, CMS predicts national health spending to grow at an average annual rate of 5.4% through 2028.

Value-based pricing is a critical tool in addressing affordability and access. At Novartis, we price our medicines in consideration of the value they bring to patients and society. When setting the prices of our medicines, we consider multiple factors, including the improvements they offer to patients both clinically and in terms of their quality of life, and the benefits they offer to the healthcare system and society more generally.

Novartis has been a leading advocate for an industry-wide shift to value-based pricing and reasonable out-of-pocket costs for patients. We believe a value-based system of reimbursement will encourage the use of the most cost-effective medicines and treatments available and increase access to effective and affordable care by addressing inefficiencies and quality issues.

We view the hallmarks of a value-based system as follows:

- *It is patient-centered:* by systematically measuring patient outcomes and costs, value-based systems can reduce both ineffective health interventions and avoidable complications. Transparent health outcomes and healthcare cost data enable patients and healthcare professionals to make informed choices, give providers an incentive to improve the quality of their services, and spur competition to deliver better outcomes.
- *It is more efficient and sustainable:* by setting and rewarding a common and measurable goal, all stakeholders are encouraged to work together across the healthcare system to coordinate care and optimize results, rather than focusing only on their individual input. Outcomes and cost data allow providers to benchmark their performance and learn from peers that consistently achieve the best results. By identifying interventions that work, the healthcare system can stop wasting resources on those that do not, and shift funding across budget lines to where outcomes are achieved at the lowest possible cost. For example, where medicines can reduce hospital spending, funds can be allocated accordingly. Therapies targeted at a well-defined patient population can reduce waste given their high probability of response. Following loss of exclusivity, biosimilar and generic medicines should allow health systems to maintain the same level of outcomes at lower cost. These savings can be used to expand access to existing and innovative therapies.
- *It drives research agendas and investment in the areas of highest value for patients:* drug developers can deliver value in the form of innovative medicines and new value-adding features of existing medicines, biosimilars, and generics. Rewarding interventions that deliver the best possible value for patients, health systems, and society set the right incentives to develop and deliver effective and efficient care.

Unfortunately, our current system discourages the use of true value-based pricing or contracting approaches for pharmaceuticals. Barriers, such as the Best Price and other government

reporting requirements, prevent manufacturers like Novartis from taking on greater financial risk in value-based arrangements. Addressing those barriers will enable manufacturers to take on more financial risk and more directly tie the price of a therapy to the value it delivers to individual patients.

We encourage healthcare stakeholders to shift to a value-based pricing approach that can ensure patient access to innovative medicines that are priced based on the value they deliver, with reasonable patient out-of-pocket costs.

While we work to engage stakeholders in a new approach that rewards what matters most – the best outcomes for patients, healthcare systems, and society – we continue to work within today’s complex U.S. system to lower the prices paid by patients at the pharmacy counter.

To do that, we are investing heavily in generics and biosimilars and ensuring access to drugs patients need but cannot afford.

### *B. The Role of Generics and Biosimilars*

We encourage the greater use of generics as an effective way to hold down drug spending and increase access to affordable care. We are developing lower-cost biosimilars and generics through our Sandoz division. Sandoz brought the first biosimilar to market in the U.S. and is the third-largest generics and biosimilars company in the U.S.

Ninety percent of prescription drugs dispensed in the U.S. are generics, and the U.S. healthcare system has saved over \$2 trillion over the last ten years through their use. We estimate that our medicines, through Sandoz generics’ business, helped save the U.S. healthcare system around \$12 billion in 2018 and \$101 billion in the last decade.

We also advocate for the faster development and improved uptake of biosimilars – copies of large molecule biologic drugs – by reducing patient cost-sharing and incentivizing physician prescribing of them. Sandoz – a global leader in biosimilars – has eight biosimilars approved globally and more than 10 in the pipeline.

### *C. Ensuring Access to Lifesaving Medicines*

We believe that medicines should be available to all who need them, and that we have a responsibility to make our products available to those who cannot afford them. In late 2017, we committed to systematically integrate access strategies into how we research, develop, and deliver our new medicines globally and established the Novartis Access Principles. These strategies include adopting innovative pricing and access models, refocusing research and development based on society’s healthcare needs, and supporting approaches to strengthen healthcare systems.

In the U.S., through the Novartis Patient Assistance Foundation (NPAF), we provided approximately \$2.7 billion in free medications to more than 87,000 patients, covering 75 medicines in our portfolio in 2019. Individuals making \$75,000 or less per year can qualify for free medicines. The eligibility threshold increases as family size increases. Through the NPAF, we have expanded access to Novartis medicines launched in 2019, including treatments for wet age-related macular degeneration, multiple sclerosis, and breast cancer. In addition, NPAF’s Institutional Patient Assistance Program (IPAP) now includes ophthalmology and cardiovascular products and has increased its partnerships with safety-net clinics, which provide healthcare services to indigent populations in the U.S. IPAP clinics receive Novartis medications directly and handle patient enrollment and processing. This allows patients to walk in and receive the medicines they need almost immediately, filling a critical gap in the healthcare system.

In addition, every year, Novartis helps thousands of patients with commercial insurance – approximately 520,000 such patients in the U.S. in 2019 alone – access our medicines at

reduced cost to them. Through our co-pay assistance programs in the U.S., eligible patients pay no more than \$30 for a 30-day prescription for the vast majority of our branded and biosimilar products, including our cancer portfolio. Our co-pay assistance programs are subject to limits imposed by a patient's individual health plan, pharmacy benefits manager, or employer, and applicable laws. Under current regulations, co-pay assistance is not available to patients covered by government healthcare programs, such as Medicare and Medicaid.

Until we achieve meaningful healthcare reform that reduces patients' cost, we will continue to serve as a stop-gap for patients who need assistance affording their medicines. As stated previously, we believe that meaningful reform can happen through the adoption of value-based pricing and healthcare, and we are committed to collaborating with industry and policymakers to make that a reality.

Globally, we ranked second on the 2018 Access to Medicine Index. In 2019, our products reached approximately 800 million patients globally, 16 million of which were through access programs such as Malaria Initiative, Healthy Family, and Novartis Access. We also remain committed to combating neglected tropical diseases such as malaria, leprosy, Chagas disease, and sickle cell disease.

Since 2001, Novartis has delivered more than 900 million antimalarial treatments, including more than 390 million treatments for children. We have also initiated a new formulation of our antimalarial product for infants weighing less than 11 pounds. Over the last two decades, we have provided free multi-drug therapy to seven million leprosy patients. Last year, we joined the Global Chagas Disease Coalition and recruited 900 Chagas disease patients for a first-of-its-kind clinical trial in patients with Chagas-related heart failure. We have also delivered more than 20,000 hydroxyurea treatments to Ghana to treat patients with sickle cell disease. Novartis is also providing sickle cell disease education and awareness in the U.S., while advocating for the advancement of our sickle cell disease policy principles, which seek to address health disparities.

### **3. Our Response to the Coronavirus Pandemic**

The coronavirus pandemic has demonstrated the importance of a vibrant and innovative pharmaceutical industry which is flexible enough to pivot to address a new global health crisis. It has also highlighted the value the industry delivers to society.

We have quickly mobilized R&D capabilities, medicines, clinical trials expertise, and philanthropic aid to address the pandemic. We have committed to donating \$40 million to support communities around the world affected by the pandemic. This includes financially supporting more than 30 organizations in the U.S. such as Americares, Feeding America, and the Cancer Support Community. And Novartis has been active in two key cross-industry research initiatives, the COVID-19 Therapeutics Accelerator, coordinated by the Bill & Melinda Gates Foundation, Wellcome, and Mastercard, as well as a COVID-19 directed partnership organized by the Innovative Medicines Initiative.

The company is also supporting COVID-19 related clinical investigations of several Novartis medicines. To support access, Sandoz became the first company to commit to keeping stable prices for a basket of essential medicines that may help in the treatment of COVID-19 and entered into a partnership with U.S.-based Civica Rx to support a stable supply of essential generic hospital medicines.

We are making 15 drugs that treat key symptoms of COVID-19 available to low- and lower-middle income countries at zero profit until a vaccine or curative treatment is found. Furthermore, Novartis Gene Therapies – formerly known as AveXis – entered into a

manufacturing agreement with Massachusetts Eye and Ear and Massachusetts General Hospital to produce its novel genetic COVID-19 vaccine candidate called AAVCOVID.

None of this would have been possible without the tremendous efforts of our associates all around the world. I would like to take this opportunity to acknowledge that and offer my deepest thanks to all who have been working tirelessly on our response throughout this year – often under very difficult personal circumstances.

#### **4. Conclusion**

In recent decades, trust in the pharmaceutical industry has eroded, and our industry must work to regain it. At Novartis, we understand that this trust is earned not just from bringing transformative medicines to patients, but by pricing these medicines responsibly and ensuring broad access. We are passionately committed to this purpose.

#### **Appendix – Innovation in the Treatment of Chronic Myeloid Leukemia**

Novartis' purpose – to reimagine medicine to improve and extend people's lives – is reflected in the long-standing commitment we have to the development of life altering medicines for the treatment of chronic myeloid leukemia (CML). Gleevec is a strong example of that commitment, representing what many continue to view as a sea change in the treatment of the disease. To fully comprehend the impact of Novartis on the treatment of CML and our commitment to continued development of new treatments, it is important to first understand the deadly nature of CML and the evolution of CML treatment options prior to the approval of Gleevec.

##### *A. Background on Chronic Myeloid Leukemia*

CML is a type of cancer in which the body produces cancerous white blood cells. Almost all patients with CML have an abnormality known as the “Philadelphia chromosome,” which produces a protein called Bcr-Abl. Bcr-Abl causes malignant white blood cells to proliferate. Worldwide, CML accounts for approximately 10% to 15% of all adult cases of leukemia, with an incidence of one to two cases per 100,000 people per year.

##### *B. Development and Introduction of Gleevec by Novartis*

Novartis' decades-long commitment to the development of Gleevec began with the oncology research efforts of Alex Matter, M.D., who since 1983 had been building a cancer research unit for Ciba-Geigy (which, in 1996, became Novartis) focused primarily on kinase inhibitors. Dr. Matter and his team identified several compounds with potential activity against Bcr-Abl. From a pool of several promising compounds, the scientists were particularly optimistic about the unique properties of one. It soon became the group's “lead compound.” Other Ciba-Geigy scientists then began the challenging process of trying to refine the activity of the lead compound against Bcr-Abl by adding, modifying, or deleting structural elements. After two years of painstaking experimentation, the team turned the compound – a weak, non-specific inhibitor – into a potent, specific inhibitor of Bcr-Abl. The new agent effectively blocked the enzyme that leads to the proliferation of white blood cells seen in patients with CML.

In 1993, building on the enormous experimental achievement of those Ciba-Geigy scientists, Ciba-Geigy began collaborating with Brian Druker, M.D., who had previously advised Ciba-Geigy scientists during identification of the compound and possessed substantial expertise in tyrosine kinases and CML. Dr. Druker worked closely with Ciba-Geigy to profile the activity of the compound (first called STI571 and then Gleevec) in cellular models of CML. After extensive work, Dr. Druker and Ciba-Geigy discovered that STI571 suppressed the proliferation of cells resulting from Bcr-Abl activity, the hallmark of CML. On May 1, 1996, Dr. Druker published in

the *Journal of Nature Medicine* the first report on the remarkable results of his work with Ciba-Geigy on STI571. For the next several years, Ciba-Geigy and then (after Ciba-Geigy became Novartis) Novartis conducted additional research and initial chemical and pharmaceutical development that was needed to start clinical trials of STI571, including elaboration of the chemical synthesis, studies of drug formulation, pharmacokinetics, and toxicology screenings. Results from the initial oral bioavailability and toxicology studies were promising, but not optimal, and Novartis undertook additional refinements of the compound.

In June 1998, Novartis initiated the Phase I clinical trials for Gleevec. The Company enrolled 149 patients, a large number for a Phase I trial, partially because the research findings were so positive. Between September 1998 and April 1999, Novartis scientists realized that Gleevec had unusually significant activity against CML. Nearly every patient who took the drug was responding. Apprised of the preliminary data, Novartis management and senior researchers elected to do additional pre-clinical research – even repeating some earlier studies – on the pharmacodynamics of the compound. This additional work was intended to support the design of the Phase II studies by broadening and solidifying the Phase I database. By April 1999, the pre-clinical studies were concluded, and the Phase I clinical trials continued to progress smoothly.

In April 1999, the Company began the manufacture of larger quantities of development drug substance batches. At approximately the same time, the final drug product formulation and manufacturing process had been developed and batch sizes had already reached pilot scale. With the unprecedented treatment outcomes in Phase I, however, there was demand for Gleevec from thousands of patients. Novartis realized that it would have to produce commercial quantities of Gleevec as many as four years earlier than planned. Novartis took a huge business risk by scaling up development and production to multimillion-dollar levels for a drug in very early-stage development. In addition, Novartis asked its team to shave a year off the Company's typical drug development time and accelerate the regulatory filing for Gleevec worldwide to early 2001. To reach its goal of making Gleevec available to thousands of patients instead of dozens in a significantly tighter timeframe than ever before, the entire Company committed to shortened timelines.

Novartis reorganized its product pipeline, giving Gleevec a top development priority from among approximately two-dozen major projects in late-stage development. For a drug in the early stages of development that treats a relatively small patient population, and with only preliminary data from small trials to support it, the scope of resources dedicated to Gleevec and risk assumed by the company was remarkable.

Novartis enrolled almost 1,000 patients in Phase II clinical trials. In addition, in April 2000, after discussion with representatives of the US National Cancer Institute (“NCI”), FDA, and advocacy groups representing patients with CML, Novartis initiated a clinical trial expanded access program. The sole purpose of the program was to provide appropriate access to Gleevec to appropriate patients. A total of 7,380 patients participated in the program and received Gleevec at no cost through the trials until it became commercially available to them. The information gained from the program would not be a prerequisite for the registration packages; therefore, it represented another huge financial investment by the Company at an early stage of development to provide access to Gleevec to all CML patients.

In June 2000, Novartis initiated Phase III trials. Overall, the clinical trials for Gleevec involved more than 2,000 patients in phase I-III studies in approximately 180 centers. On February 27, 2001 – approximately 2.7 years after the first clinical trial was initiated – the Company began submitting new drug applications for Gleevec to health authorities globally. On March 7, 2001, just eight days later, the FDA granted Gleevec a priority review. On May 10, 2001, only 10

weeks after submission of the New Drug Application, the FDA granted approval of Gleevec – marking the fastest review period by FDA of any cancer drug. Gleevec was indicated for the treatment of adult patients with Philadelphia chromosome-positive CML in the blast crisis, accelerated phase, or in chronic phase after failure of interferon therapy.

### *C. Continued Investment in Gleevec*

Much of the early research surrounding Gleevec was focused on CML, due to the evidence that a single pathway (Bcr-Abl), which Gleevec was thought to inhibit, was responsible for the disease.

However, the Company also believed that Gleevec could be effective as a therapy for gastrointestinal stromal tumor (“GIST”) – a rare solid tumor. Clinical data demonstrated that partial responses were seen in more than 50% of patients. Based on the early data, the FDA approved Gleevec for the GIST indication on February 1, 2002.

Novartis investment in Gleevec continued following its approval in CML and GIST. As a result, many other patients have benefited from the extensive research investment of the Company in Gleevec, which eventually identified five other rare diseases for which Gleevec can benefit patients: (a) PH+ Acute lymphoblastic leukemia; (b) Myelodysplastic/Myeloproliferative diseases (“MDS”/“MPD”); (c) Aggressive systemic mastocytosis (“ASM”); (d) Hypereosinophilic syndrome (“HES”); and (e) Metastatic dermatofibrosarcoma protuberans (“DFSP”).

Novartis’ development of Gleevec to treat CML is one of the most significant pharmaceutical innovations in the treatment of cancer. The unique methods used by Novartis to discover, develop, and manufacture Gleevec have drawn attention from researchers, manufacturers, and patients worldwide. While Novartis no longer has access to much of the Gleevec development spend data, the majority of which occurred over two decades ago, the Company efforts to develop and distribute Gleevec were extraordinary and unprecedented. Upon learning about the potential impact of Gleevec, Novartis took significant business risks to prioritize Gleevec’s development and increase patient access to clinical trials. Novartis also reallocated resources and employees Company-wide to speed development of its revolutionary drug and provide it to patients in desperate need. Finally, even after the FDA approved Gleevec for CML, Novartis continued to expend significant resources to conduct extensive research in the hope that Gleevec could be effective in treating other diseases.

### *D. Novartis has Continued to Develop New and Better Treatments for CML*

Gleevec was the first of many new therapies developed through an advanced understanding of the molecular biology of cancer. It has helped change the way cancer drugs are developed and manufactured. Novartis continued to revolutionize oncology research and built upon its existing knowledge of CML by developing Tasigna, a second-generation tyrosine kinase inhibitor which was proven to be more effective than Gleevec as a treatment for CML in a head-to-head clinical trial. Tasigna’s effectiveness opened up the possibility that patients could experience treatment free remission, in which a patient’s CML is under control to such a degree that under close observation and monitoring they are able to stop treatment. Tasigna was the first drug to have treatment free remission data in its label. Novartis has continued its commitment to CML through its work today on the investigational treatment asciminib (ABL001), which is currently in clinical trials to potentially expand care to patients with CML that has continued to progress.